## REMARKS

Claims 5, 8, 9, 12-14, 39, and 42 will be pending before the Examiner upon entry of the above amendments. Claims 1-4, 6-7, 10-11, 15-38, 40-41, and 43-49 have been canceled without prejudice, and Applicants reserve the right to pursue the subject matter of the canceled claims in a related application. Claims 5, 9, and 12 have been amended. Support for the amendments to claims 5, 9, and 12 may be found in the claims as originally filed and through out the specification, *e.g.*, at pages 1-5; and Table 11 at pages 132-133. Thus, the amended claims are fully supported by the instant specification and no new matter has been introduced.

***Specification:***

The Examiner objected the instant specification for the following reasons: (1) the priority claim refers to the '568 application, but does not indicate the relationship of the '568 application and instant application; (2) the title of the invention is not descriptive; (3) the specification contains embedded hyperlink (*e.g.*, at page 13, line 19, and page 15, line 7); and (4) the disclosure contains typographical errors (*e.g.*, at page 38, line 6, and page 113, line 31).

Applicants respectively submit that the instant specification has been amended accordingly, and the objections should be withdrawn.

***Claim Rejection:***

**1. The Rejections Under 35 U.S.C. § 101 Should Be Withdrawn**

Claims 5-14, 39 and 42 are rejected under 35 U.S.C. § 101 for not being supported by a specific and substantial asserted utility or a well-established utility. According to the Examiner, "none of the teachings with regard to the asserted utilities are specific to the claimed invention" (see Office Action, page 10, last paragraph), and functions of a protein cannot be predicted based solely on structural similarity to a protein found in the sequence database.

Applicants respectfully submit that the instant specification teaches that the claimed nucleic acids can be used, *inter alia*, to differentiate certain cancer tissues, *e.g.*, certain breast cancer or certain ovarian cancer tissues, from their corresponding normal tissues, *e.g.*, normal breast tissues or normal ovarian tissues. The instant specification at, *e.g.*, page 93, line 31, to

page 95, line 14, teaches how to detect the claimed nucleic acids in a biological sample. The instant specification further teaches, *e.g.*, at page 118, Table 6, Panel 1.2, page 122, Table 8, Panel 2D, that a nucleic acid molecule comprising SEQ ID NO: 1 is highly expressed in certain cancer tissues, *e.g.*, certain breast cancer or certain ovarian cancer tissues, as compared to their corresponding normal tissues, *e.g.*, normal breast tissues or normal ovarian tissues. Table 30 (pages 28-31) of the instant application and Appendix 1 attached hereto further demonstrate that other claimed nucleic acid sequences are highly homologous to SEQ ID NO:1, and thus have the same utility. Therefore, the specification clearly teaches the use of the claimed nucleic acids for differentiating certain cancer tissues from their corresponding normal tissues, of which use is specific, substantial and credible.

The Examiner's attention is further invited to the case law and M.P.E.P., which state that Applicants only need to assert one specific, substantial and credible utility of the claimed invention:

> It is common and sensible for an applicant to identify several specific utilities for an invention, particularly where the invention is a product (*e.g.*, a machine, an article of manufacture or a composition of matter). However, regardless of the category of invention that is claimed (*e.g.*, product or process), an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112; additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility.

M.P.E.P. § 2107.02, I (Eighth Edition, August 2001, revised February 2003). Since the instant specification teaches a specific, substantial and credible utility, *i.e.*, to differentiate certain cancer tissues, *e.g.*, certain breast cancer or certain ovarian cancer tissues, from their corresponding normal tissues, *e.g.*, normal breast tissues or normal ovarian tissues, the rejection under 37 U.S.C. § 101 should be withdrawn.

**2. The Rejections Under 35 U.S.C. § 112, Written Description, Should Be Withdrawn**

Claims 5-14, 39 and 42 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner states that the specification fails to disclose which of the sequence "variants" actually have endozepine-related protein precursor-like activities and physiological function.

Applicants respectfully submit that all the variants as defined in the amended claims are sufficiently described in the specification, and can be used for the asserted utility. As such, the rejection under 35 U.S.C. § 112, first paragraph, for lacking of written description, should be withdrawn.

### 3. The Rejections Under 35 U.S.C. § 112, Enablement, Should Be Withdrawn

Claims 5-14, 39, and 42 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. In particular, the Examiner contends that (1) since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, one skilled in the art clearly would not know how to use the claimed invention; and (2) even if a specific and substantial utility is asserted, using the claimed invention for any of the purposes set forth in the specification would require undue experimentation.

Applicants have asserted a specific and substantial utility as discussed in subsection 1 above, and the specification in Example 2 (at pages 108-130) fully enables a skilled artisan to use the claimed nucleic acids for the asserted utility. Thus, the rejection under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement, should be withdrawn.

### 4. The Rejections Under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

Claims 5-7, 10-14, 39 and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Examiner states that the metes and bounds of the claimed subject matter of claim 5 are unclear.

Applicants respectfully submit that claim 5 as amended has set clear metes and bounds of the claimed subject matter. As such, the rejection under 35 U.S.C. § 112, second paragraph, should be withdrawn.

### 5. The Rejections Under 35 U.S.C. § 102 Should Be Withdrawn

Claims 5-7, 9-14, 39 and 42 are rejected under 35 U.S.C. § 102(a) as being anticipated by Shimkets et al., WO 00/78802 (12/18/2000) ("Shimkets"). In particular, according to the Examiner, Shimkets discloses a nucleic acid comprising a sequence that is 98.6% identical to the instant SEQ ID NO: 51, and encodes a polypeptide that is 98.5% identical to the instant SEQ ID NO: 52.

Claims 5, 7, 9-12, 14, 39 and 42 are rejected under 35 U.S.C. § 102(b) as being anticipated by Webb et al., (1987) DNA 6:71-79 ("Webb") as evidenced by Sanger et al. (1977), Proc. Natl. Acad. Sci. USA 74:5463-5467 ("Sanger"). In particular, according to the Examiner, Webb discloses a nucleic acid encoding a polypeptide that is 85% identical to the instant SEQ ID NO: 52.

Applicants respectfully submit that the nucleic acid sequence disclosed in Shimkets, which is 98.6% identical to the instant SEQ ID NO: 51, is not a work of "another," which is required by 35 U.S.C. § 102(a). Specifically, the co-inventors Corine Vernet and Ferenc Boldog of the instant application are also the inventors for the subject matter directed to the nucleic sequence disclosed in Shimkets that is 98.6% identical to the instant SEQ ID NO: 51 (the other named co-inventors in Shimkets are inventors for other claimed subject matter in that application). Applicants will submit a 37 CFR 1.131 affidavit if the Examiner deems necessary.

With respect to the 102(b) rejection based on Webb and Sanger, Applicants respectfully submit that the claims as amended no longer encompass the nucleic acid disclosed in Webb.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 102 be withdrawn.

***Double Patenting:***

Claims 5-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-28 of co-pending USSN 10/287,971. According to the Examiner, claims 20-25 of the '971 application anticipate the claims of the instant application. The Examiner further states that "a showing that the invention were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. § 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. § 102(f) or (g), or 35 U.S.C. § 102(e) for applications filed on or after November 29, 1999." See Office Action, page 23, second paragraph.

Applicants respectfully submit that CuraGen Corporation is the owner of both the '971 application and the instant application by assignments. Moreover, different subject matter is currently pursued in the '971 application, *i.e.*, Applicants have elected nucleic acids of or related to SEQ ID NOs:223/224 (Internal ID No. CG57094) in the '971 application, of

which sequences are different from the claimed nucleic acid sequences in the instant application.

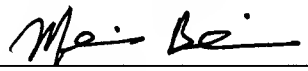
In view of the foregoing, Applicants respectfully request that the rejection for double patenting be withdrawn.

## CONCLUSION

Applicants respectfully request that the amendments and remarks made herein be entered and made of record in the file history of the present application. Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

Date: February 28, 2005



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Appendix 1: ClustalW Alignment of SEQ ID NO: 2 and SEQ ID NO:52 of the Instant Application

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475CIP_SEQ_2     1 ---MFQFHAGSWESWCCCCLIPADRPWDRGQHWQLEMADTRSVHETRFEAAVKVIQSLPK  57
475CIP_SEQ_52    1 MSTMFQFHAGSWESWCCCCLIPADRPWDRGQHWQLEMADTRSVHETRFEAAVKVIQSLPK  60

475CIP_SEQ_2    58 NGSFQPTNEMMLKFYSFYKQATEGPCKLSRPGFWDPIGRYKWDAWSSLGDMTKEEAMIAY 117
475CIP_SEQ_52   61 NGSFQPTNEMMLKFYSFYKQATEGPCKLSRPGFWDPIGRYKWDAWSSLGDMTKEEAMIAY 120

475CIP_SEQ_2   118 VEEMKKIIETMPMTEKVEELLRVIGPFYEIVEDKKSGRSSDITS----------LGNV 166
475CIP_SEQ_52  121 VEEMKKIIETMPMTEKVEELLRVIGPFYEIVEDKKSGRSSDITSVRLEKISKCLEDLGNV 180

475CIP_SEQ_2   167 LTSAPNAKTVNGKAESSDSGAESEEEEAQEEVKGAEQSDNDKKMMKKSADHKNLEVIVTN 226
475CIP_SEQ_52  181 LTSTPNAKTVNGKAESSDSGAESEEEEAQEEVKGAEQSDNDKKMMKKSADHKNLEVIVTN 240

475CIP_SEQ_2   227 GYDKDGFVQDIQNDIHASSSLNGRSTEEVKPIDENLGQTGKSAVCIHQDINDDHVEDVTG 286
475CIP_SEQ_52  241 GYDKDGFVQDIQNDIHASSSLNGRSTEEVKPIDENLGQTGKSAVCIHQDINDDHVEDVTG 300

475CIP_SEQ_2   287 IQHLTSDSDSEVYCDSMEQFGQEESLDSFTSNNGPFQYYLGGHSSQPMENSGFREDIQVP 346
475CIP_SEQ_52  301 IQHLTSDSDSEVYCDSMEQFGQEESLDSFTSNNGPFQYYLGGHSSQPMENSGFREDIQVP 360

475CIP_SEQ_2   347 PGNGNIGNMQVVAVEGKGEVKHGGEDGRNNSGAPHREKRGGETDEFSNVRRGRGHRIQHL 406
475CIP_SEQ_52  361 PGNGNIGNMQVVAVEGKGEVKHGGEDGRNNSGAPHREKRGGETDEFSNVRRGRGHRLQHL 420

475CIP_SEQ_2   407 SEGTKGRQVGSGGDGERWGSDRGSRGSLNEQIALVLMRLQEDMQNVLQRLQKLETLTALQ 466
475CIP_SEQ_52  421 SEGTKGRQVGSGGDGERWGSDRGSRGSLNEQIALVLMRLQEDMQNVLQRLQKLETLTALQ 480

475CIP_SEQ_2   467 AKSSTSTLQTAPQPTSQRPSWWPFEMSPGVLTFAIIWPFIAQWLVYLYYQRRRRKLN--  523
475CIP_SEQ_52  481 AKSSTSTLQTAPQPTSQRPSWWPFEMSPGVLTFAIIWPFIAQWLVYLYYQRRRRKLNLE  539
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